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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,628	01/23/2004	Carter R. Anderson	20030304.OR1	7719

23595 7590 08/31/2010

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
08/31/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,628	ANDERSON ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-67 and 78-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *60-67 and 78-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/18/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendments and Arguments filed on 06/09/2010.

- Claims 60 and 69 have been amended.
- Claims 1-59, 68, 72 and 76-77 have been cancelled.
- Claims 78-81 have been added.
- Claims 60-67and 78-81 are pending in the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 05/18/2010 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60-67 and 78-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 60-67 and 78-81 recite the newly amended limitation of "a first amount of carbon and second amount of carbon that has been pre-" however, the specification as-filed does not provide a written description or set forth the metes and bounds of this phrase. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, introduce new concepts and thus violate the written description requirement of the first paragraph of 35 U.S.C. §112.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to identify sufficient written support in the original specification for the "limitations" indicated above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 60-67 and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcenyac et al (US 2004/0146547) in view of Hekal (US 6,279,736) and Sackler (US 2003/0068392).

Claims are drawn to a disposal system for skin-worn transdermal patch devices containing abusable substances, a layer containing anti-abuse substance such as antagonists, a disposable container containing activated carbon and irritant, and closure means for closing said container.

Marcenyac teaches an article (a transdermal patch) includes a reservoir housing a dye and/or medicament inactivating agent (which would read on anti-abuse substance) in communication with the reservoir that is released when the reservoir is opened or revealed (0009). And further, the article may include a pocket (which would read on flexible pouch) having a sealable opening and formed between first and second portions of the opposite side of the inner layer, wherein the opening is optionally sealed by a flap covered at least in part by a permanent pressure (0014). The disposing of a transdermal patch includes placing a transdermal patch within the article, sealing the patch (which would read on adhesive seal) within a pocket of the article, such that the article releases the inactivating agent when the reservoir is opened and thus the article prevents of hinders misuse of the active agent contained in the transdermal dosage form or the disposal of the above article by folding the article so that opposite sides of the medicament layer are permanently sealed by the second adhesive (0022 and 0029). Further, article includes a medicament layer containing an opiate e.g. fentanyl; the inactivating agent include narcotic antagonists such as naloxone, naltrexne and

nalmefene; or irritating agents such as scopolamine, ketoamine, atropine or mustard oils or any combinations thereof (0112 and 0114). And in practice, if the active agent in a transdermal patch to be disposed of by placing it in the present article were an opioid, the inactivating agent renders the active agent unavailable through inactivation, such as for example chemical inactivation or alteration of the receptor binding site of the active agent; biounavailability; physical unavailability; loss of appeal of the active agent to the abuser, such as for example, an inactivating agent which creates an intolerably bad taste or an intolerable reaction such as extreme nausea or the like; or something similar thereto. One or more inactivating agent(s) may be used. Similarly, the inactivating agent could be a non-opioid with distressing or dysphoric properties if absorbed that made abuse unappealing (0099 and 0100). Additional disclosure includes that it is known in prior art (US 5,804,215) to Cubbage et al. relates to disposal system for a transdermal patch comprising a pouch for transport of the patch and disposal system encapsulates a trasndermal patch and prevents access to it.

Note, Marcenyac et al. teaches use of various anti- abuse substances directly related to effective in preventing abuse, were an opioid, the inactivating agent could be a chemical or denaturing agent that would alter residual opioid molecules in the dosage form and make them inactive (0100). Since the inactivating agents is directly related to anti-abuse substance, and the prior art teaches the same subject matter (disposable of transdermal patch containing residual or unused opioid in a separate pouch) by similar process, it is examiner's position that, in the absence of evidence to the contrary, a suitable specific anti- abuse substance is also either anticipated by Marcenyac, or

obviously provided by practicing the invention of prior art. It should be noted that where claimed and prior art products are shown to be identical or substantially identical in composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. See MPEP § 2112.01.

Marcenyac fails to teach activated carbon as anti-abuse substance in a disposable container and irritant in combination thereof.

Hekal teaches a barrier pack comprising a cover portion bonded to a base portion to form a sealed unit package wherein: a) the cover portion comprises at least one cavity capable of containing and dispensing a product (the product may be medicament or pharmaceutical in the form of tablets, capsules, pills or the like: b) the base portion is in relation to the cover portion such that the cavity extends outwardly from the base portion, the base portion comprising an absorbing agent material applied to an interior of the base portion (col. 1 lines 58-65+ and col. 2 lines 7-14). The absorbing agent containing layer contains activated carbon, carbon black. The suitable absorbing agent is chosen so as to achieve absorption of the desired vapor for the desire end use (col. 2 lines 33-48).

Sackler teaches a transderaml delivery system, such as transdermal patches comprising an opioid agonist contained in a reservoir or a matrix, anti-abuse substance such as naloxone or naltrexone and an irritant such as capsaicin. Additional disclosure includes that the transdermal formulations, e.g., the technologies described with the

inclusion of an aversive agents comprising various irritants and antagonist, such that the dosage form deters abuse of the opioid therein (0052, 0058, 0183-0190).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate activated charcoal into the Marcenyac's transdermal patch. The person of ordinary skill in the art would have been motivated to make those modifications because Hekal teaches that the absorbing agent such as activated charcoal has the capability of absorption of products (medicaments or pharmaceutical like tablets), or absorption of desired vapor or gases for the desired end use and reasonably would have expected success because the activated charcoal has power to adsorb various chemical and drug overdoses.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate irritating agent and activated charcoal into the Marcenyac's transdermal patch. The person of ordinary skill in the art would have been motivated to make those modifications because Sackler teaches that incorporation of an irritating agent (capsaicin) discourage an abuser from tampering with the dosage form and imparts a burning or discomforting quality to the abuser to preferably discourage the inhalation, injection, or oral administration of the tampered dosage form and preferably to prevent the abuse of the dosage form (0052). Therefore, one of ordinary skill in the art would have had a reasonable expectation of success because both Marcenyac and Sackler teaches a transdermal patch that can be used in the same field of endeavor, such as for example chemical inactivation or biounavailability; physical unavailability of residual amounts of abusable substance, such as for example, an

inactivating agent which creates an intolerably bad taste or imparts a burning or discomforting quality to the abuser to preferably discourage the inhalation, injection, or oral administration of the tampered dosage form.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./
Examiner, Art Unit 1618

/Jake M. Vu/
Primary Examiner, Art Unit 1618